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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,946	09/29/2003	Ashish Varma	PA1436	8308

28390 7590 04/30/2007
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/30/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/30/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/671,946

Applicant(s)

VARMA ET AL.

Examiner

Krisanne Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 9-13, 15-17, 18-21 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over George U.S. patent No. 5,014,494 in view of Lee et al., U.S. publication 2003/0083616 A1.

George teaches a method of sterilizing a sensitive polymeric medical device wherein the device is packaged in a gas impermeable package, nitrogen is used to purge any oxygen from the package, and the package is irradiated with either electron beam or gamma radiation to sterilize the device. The package material is preferably a multilayer material with polymeric layers and an aluminum layer, the aluminum layer providing the greatest oxygen barrier. See column 1, lines 20-25 and column 2 lines 10-55.

Lee et al., teaches that it is known and expected that dilation catheter balloons are sensitive polymeric medical devices that benefit from radiation sterilization. Radiation sterilization of the balloons is performed with the balloon packaged in a multilayer pouch formed from a polyester layer, aluminum foil layer and a polyethylene layer. The balloons themselves are recognized as being generally formed from polyether-block co-polyamides, nylons, and PET. Atmospheres within the pouch are inert by flush with a gas such as nitrogen to protect the device from deleterious oxidation. Radiation is applied at doses levels generally between 25 and 75 kGys. See

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page 8, paragraphs 0097, 0098 and 0107, page 10, paragraphs 0128 and 0134, page 11, paragraphs 0138-0140, page 16, Examples 16 and 17, and page 17, Examples 18-19

It would have been obvious to one of ordinary skill in the art to apply the method of George to the packaged balloon as taught in Lee et al, because it is recognized that such balloons benefit from radiation sterilization, and the control of the method of George would minimize any deleterious effects of that sterilization on the polymeric balloon.

With respect to claims 1 and 11, it would have been obvious to one of ordinary skill in the art to arrange the layers of the multilayer packaging in any configuration, absent any showing of unexpected results achieved thereby, as the prior art clearly teaches the efficacy of each of the claimed layer materials in sterilization packaging for use with polymeric articles and ionizing radiation sterilization.

Claims 1-3, 5-13 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahlqvist et al., U.S. patent No. 5,881,534 in view of Lee et al., '616.

Ahlqvist et al., teach sterilization of sensitive polymeric medical devices by placing the device in a gas impermeable multilayer package preferably including an aluminum foil layer, purging oxygen from the package with an inert gas such as nitrogen and irradiating the packaged device with either electron beam or gamma radiation at claimed dose levels. The package includes an oxygen absorbent to ensure minimal levels of oxygen to prevent polymeric deterioration thereby. Ahlqvist et al., are silent as

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to the specific application of the method to balloons. See the abstract, column 5, lines 10-45, column 6, lines 5 –55 and column 7, lines 33-35.

Lee et al., is applied as set forth above.

It would have been obvious to one of ordinary skill in the art to apply the method of Ahlqvist et al., to the packaged balloon as taught in Lee et al, because it is recognized that such balloons benefit from radiation sterilization, and the control of the method of Ahlqvist et al., would minimize any deleterious effects of that sterilization on the polymeric balloon.

With respect to claims 1 and 11, it would have been obvious to one of ordinary skill in the art to arrange the layers of the multilayer packaging in any configuration, absent any showing of unexpected results achieved thereby, as the prior art clearly teaches the efficacy of each of the claimed layer materials in sterilization packaging for use with polymeric articles and ionizing radiation sterilization.

Response to Arguments

Applicant's arguments filed 2/15/2007 have been fully considered but they are not persuasive. Applicant argues that none of the references applied teach the arrangement of the three layers of the pouch as now claimed in independent claims 1 and 11, however, the Examiner would maintain that the prior art clearly teaches the conventionality of the materials in each of the three layers and in the absence of any showing of unexpected results the arrangement of those layers is not found to be non-obvious.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

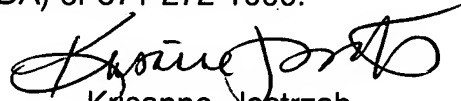
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

April 24, 2007